Product Tampering

On occasion, a telephone call may be received or an individual may come into the office concerning possible tampering of a food product, over-the-counter drug or cosmetic. Most reports have proven to be false, with the claimants seeking attention and/or profit. Another common trend are "copy cat" reports on the heels of a widely publicized tampering incident, e.g. syringe in a can of soft drink. A "red flag" indicating a possible false report is when the environmental public health specialist is contacted about the incident by an attorney or news reporter, rather than by the alleged victim.

Tampering, threat of tampering, and false reporting of tampering of food products, over-the-counter drugs, or cosmetics is a federal crime. Whenever a report of possible or actual tampering is received, referral must be made to the U.S. Food & Drug Administration (FDA) via the DHSS/BERL central office.

Authority

1. FDA is authorized to investigate reports of tampering:
    A. Federal Anti-Tampering Act (FATA), Title 18, USC, Section 1365; and
    B. Federal Food, Drug and Cosmetic Act.
2. The lead agency is FDA's Office of Criminal Investigations (FDA/OCI).
    A. FDA/OCI will coordinate notifications with appropriate law enforcement agencies, including the Federal Bureau of Investigation (FBI).

The goal of the FDA/OCI investigation is to:

1. Determine if tampering has occurred;
2. Determine the seriousness of the problem;
3. Determine the quantity of the affected products on the market;
4. If possible, determine the source of the tampering;
5. Quickly remove any contaminated products from consumers or commerce; and
6. Seek to identify and initiate criminal prosecution of those persons responsible for criminal activity associated with the tampering/threat incident.

In some cases, the FDA/OCI may decide not to follow up on reports of tampering because of resource limitations. They will then consult with the FDA district office to determine proper follow-up, which may include referral to state or local agencies, which may include DHSS/BERL.

Any information on matters under investigation by federal agencies must not be released without prior discussion and concurrence of the FDA/OCI.

Method

Reports of tampering may be received directly from the victim, perpetrator, news reporter or attorney; or by referral from the FDA. Timely communication with FDA is important for purposes of coordination and investigation.

When information is received directly from the field:

1. Information from the initial contact should be recorded:
   A. Name, address, telephone number of the victim;
   B. Product information of the item involved;
      (I) Product brand;
      (II) Flavor, variety, etc.;
      (III) Size of container; and
      (IV) Lot number, production code, UPC and/or other descriptive identifiers.
   C. Problem with the product:
      (I) Off quality (off-color, off-odor, etc); and/or
      (II) Foreign objects.
   D. If there has been resulting injury/illness:
      (I) Has physician and/or medical center been consulted?
      (II) Have the police been contacted?
      (III) Has victim volunteered that an attorney has been contacted?
      (IV) Has victim volunteered that news media has been contacted?
   E. If product or product container can be secured, arrange to assume custody of the product/container:
      (I) Do not forward to DHSS Laboratory Services unless instructed; and
      (II) Notify FDA/OCI for disposition of product/container.
8. Attempt to answer the following concerns as quickly as feasible:
   A. Has tampering occurred, or can the condition of the product be explained by other means?
   B. Is death, injury, or illness associated with the report and if so, does it appear to be isolated, or widespread?
   C. Does the incident appear to be isolated or widespread?
   D. Is it likely that other similarly affected products remain in distribution and if so, what is the extent and magnitude of the distribution?
   E. If not isolated, could the product tampering have occurred at the production facility or in the distribution chain?
   F. Does the report seem plausible; does the victim's story stay consistent?

Upon request or invitation from FDA to DHSS/BERL, personnel may inspect retail stores, distribution points and/or manufacturers relative to a tampering incident investigation.

1. The request or invitation shall be from FDA to DHSS/BERL central office.

   A. In most cases, the request of invitation will be routed to appropriate DHSS/BERL regional personnel
   B. Depending on circumstances, central office and regional personnel may be involved with the field work associated with the incident;
   C. DHSS/BERL personnel should concentrate their efforts on identifying possible avenues that products could become contaminated; and
   D. Matters concerning security at these sites, e.g. employee and visitor logs, employees with potential grudges, labor disputes, etc., should be left to the law enforcement agencies.

2. Retail Store Inspection

    a. For an isolated incident, visit the retail store where the suspect product was obtained. To help determine if the tampering occurred after stocking of the shelves or before arrival to the store:
        i. Examine other containers of the same lot number for visible signs of tampering;
        ii. Inspect what is on the store shelves; and
        iii. Inspect what is in the stock room.
    b. Obtain the relevant information about the distribution source of the product;
        i. If in Missouri, arrange for a visit to the facility for further inspection; or
        ii. If out of state, inform DHSS/BERL Central Office, who will notify FDA.
        iii. The regulatory agency for the affected area will be informed, either by FDA, or DHSS/BERL, for an inspection of the facility.
    c. For known tampering that presents an immediate health threat, e.g. cyanide in Tylenol, visits to retail outlets known to have the product should be made immediately.
        i. The products suspected of being involved shall be placed under embargo and secured.
        ii. DHSS/BERL will inform FDA/OCI of the quantity of product placed under embargo, the current location, and the site where the product was found.

3. Distribution Point

    a. Determine if the product was received from another distributor or directly from the manufacturer;
    b. Determine if product with the implicated lot number is on hand;
        i. If so, the amount should be noted;
        ii. Try to learn the amount of suspect product received and any variations from the amount consigned to the facility;
        iii. Try to ascertain if the accounts are wholesale, retail or both, and if they handle any cash and carry orders;
        iv. The distribution area covered by the facility is also needed. If possible, a listing of accounts likely to have received shipments of the product with the implicated lot number should be made; and
        v. Stock rotation practices should be noted.
            a) Determine if returns are accepted and how they are handled; and
            b) If returns of implicated products are made, are they segregated so they will not inadvertently be re-distributed?
    c) Note if there are any practices or opportunities that would allow for tampering of the product.

4. Manufacturer
    a. Inspection of a manufacturing facility can be time-consuming and exhausting. The objective is to determine if contamination of the product could have occurred at the facility. Thus, inordinate time should not be given to other sanitation aspects of the facility, e.g. don't document rodent activity by the loading dock if the tampering concern is glass shards in packages of cookies. The rodent activity should be noted, but not pursued until the next routine inspection of the facility. With the implicated product in mind:
    b. Obtain the names, titles, addresses, and telephone numbers of company representatives;
    c. If there are any contract packagers, obtain the name, location and products handled;
    d. List other facilities that may produce the product;
    e. Determine the production dates of the lot number of the affected product;
        i. Describe the lot numbering system and any plant identification numbers and expiration dates placed on product containers and cases;
        ii. Find the lot size and history of production beginning with date of receiving raw material and the dates and description of processing steps;
        iii. Note the storage history of containers of raw material and whether there are containers partially full; and
        iv. Determine distances between production areas or between processing equipment at critical points.
    f. Obtain a listing of the facility's source for raw material for the implicated product;
    g. Note any locations where an employee could have access to the contaminant being investigated;
        i. Describe the security for the suspected contaminant including limitations of access, where it is stored, and responsibility for controlling access to the material;
        ii. Describe what legitimate use, if any, the facility has for the suspected contaminant in each of the locations found; and
        iii. Determine if there is a log for the material used and, if so, obtain a copy of the log.
    h. Describe any laboratory control tests and in-process tests performed on the finished packaged product and in-process materials. Determine whether reserve samples are retained of all lots;
    i. Determine how rejects and re-worked materials are handled; and
        i. Describe any unusual events that may have taken place during the period when the suspect material was in the facility.

Record Requests – Occasionally, the investigation may require a request for information, which is considered proprietary or otherwise not normally requested or made available.

1. Under general authority of FATA, federal investigators or DHSS/BERL personnel that are FDA commissioned officers may request certain data from manufacturers, distributors, or other parties involved in the investigation if, in the opinion of supervisory personnel it is necessary, or if the following criteria are met:
    a. The apparent tampering incident may be serious and is assigned a high priority by FDA or FBI;
    b. The data sought are normally of the type that FDA authorized personnel are trained to evaluate and have access to in other areas of routine activities, e.g. production records, formulae, distribution records, etc.;
    c. The requested data are likely to be necessary to the successful resolution of the investigation; and
    d. Other alternatives to obtain the information are not as readily available.
2. If an FATA request for data is made, the DHSS/BERL FDA commissioned officer should direct a verbal request to the most responsible individual at the location;
    a. Explain clearly and concisely your need for the data under the general authority of the FATA; and
    b. Any refusal encountered during a tampering investigation should be documented and include that the above listed criteria were met and that the firm was aware of the non-routine nature of the request.
        i. Consultation will be necessary with DHSS General Counsel and a search warrant, subpoena or court order may be appropriate in some circumstances.

Sampling in tampering incidents will have precautions above and in addition to those described in the Food Sampling subsection of the Communicable Disease Investigation Reference Manual Section 4 Disease Conditions pages 18-19.

1. Whenever a sample is collected for suspect tampering:
    a. Collect an authentic sample of the same product;
    b. If possible, collect from the same lot and code; and
    c. At least 6 intact units should be obtained.
2. Any containers that a tamperer may have handled in placing the tampered product on the shelf should be collected:
    a. If law enforcement or FDA personnel are present, let them collect the containers as they have training and equipment for collecting evidence;
    b. If these personnel are not present, determine if the area where the containers are located can be secured until these personnel arrive; and
    c. If these personnel are not expected to be on-scene and/or it is likely the container evidence will be compromised, then the on-scene environmental public health specialist should collect the containers with the following precautions;
        i. Take care to avoid adding or smearing fingerprints;
            a) Wear cotton gloves, use tongs, forceps, or pick up the container by opposing corners;

b) Carefully place an identifying mark, e.g. your initials and date, on product containers in as small an area as possible (this will be important if you are called to testify); and
c) Do not open outer containers to identify inner containers or inserts.

ii. When sampling or handling product;
a) Be alert for traces of evidence such as hair, dust, paint chips, glass
b) Secure such evidence in a separate container such as a glass vial, small manila envelope or plastic bag.

iii. Take caution in packaging samples to avoid smearing and/or removing fingerprints.
a) Paper bags work best;
b) Samples should be packed to avoid movement of the product container within the bag; and
c) Place samples in a secured area, such as your locked car, until they are transferred to another responsible official.

Reporting – Reports must be submitted on a timely basis to keep affected offices in DHSS and FDA informed of latest developments.

1. The on-scene investigator shall submit at least verbal reports to DHSS/BERL central office periodically during the investigation;
2. As needed during the investigation and at the conclusion of the investigation, a written report shall be submitted to DHSS/BERL central office; and
3. Central office staff will forward information to the DEH/CDP director's office and DHSS/OPI.